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In re Application of :  
 Gregory N. Beatch et al :  
 Serial No.: 09/913,373 : PETITION DECISION  
 Filed: January 28, 2002 :  
 Attorney Docket No.: 554792000500 :

This is in response to the petition under 37 CFR 1.144, filed August 6, 2004, requesting withdrawal of an improper restriction requirement.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 371 and accepted on January 28, 2002, and contained claims 1-85, as filed. In a first Office action, mailed February 12, 2003, the examiner set forth a Lack of Unity requirement under 35 U.S.C. 121 and 372, as follows:

Group I – Claims 1-85, drawn claims where variables n, A, Q, X and Y were defined and R1-R4 were defined as non-cyclic groups;

Group II – Claims 1-85, drawn to claims where n, A, Q, X and Y were defined and R1-R2 were defined as cyclic or heterocyclic groups and R3-R4 are non-cyclic groups;

Group III – Claims 1-85, drawn to claims where variables n, A, Q, X and Y are defined and R1-R2 are non-cyclic groups and R3-R4 form a spiro-heterocyclic ring.

Group IV – Claims 1-85, drawn to claims where n, A, Q, X and Y are defined and R1-R4 are non-cyclic groups.

The examiner argued that the various groups did not make a contribution over the prior art. Also that the number of groups listed was not exhaustive and to examine all groups would impose an undue burden on the examiner. The examiner also gave applicant the option of identifying a single species from which a group would be defined and examination proceed.

Applicants replied on April 12, 2003, electing a species with traverse, but failing to give reasons for traverse.

The examiner mailed a non-Final Office action to applicants on May 7, 2003, acknowledging applicants' election of a species and drafting a group from the elected species, defining n as 1,3 or 4, Q as oxygen, X as CRRY where Y is C1-C4, R1 and R2 form a morpholinyl ring with the nitrogen to which they are attached and R3 and R4 are Hydrogen or C1-C6 alkyl or alkoxy. The examiner held all other compounds withdrawn from consideration. The examiner rejected claims 4-7 under 35 U.S.C. 101 as improper method of use claims. Claims 5, 8-71 and 74-83 were rejected under 35 U.S.C. 112, first paragraph, as lacking support in the specification and proceeded with a Wands analysis. Claims 2 and 4-7 were rejected under 35 U.S.C. 112, second paragraph, as indefinite for various reasons. No art rejection was made.

Applicants replied on November 7, 2003, with an amendment which amended claims 1-3 and 5-85, canceling claim 4. Applicants presented a traverse of the Lack of Unity requirement by the examiner as not being under the correct standard and suggested what the common special technical feature should be. Applicants further responded to the rejections under 35 U.S.C. 101 and 112, first and second paragraphs.

The examiner mailed a Final Office action to applicants on February 6, 2004, maintaining the rejection under 35 U.S.C. 112, first paragraph, for claims 6-7 and 68-69 and providing a Wands analysis supporting the rejection. The examiner objected to all other claims as containing non-elected subject matter. The examiner answered applicants' traverse of the Lack of Unity requirement with various arguments.

Applicants replied with an amendment on August 6, 2004, in which claims 1-3 and 5-85 were amended and new claims 86-89 were presented. Applicants requested withdrawal of the Lack of Unity requirement and concurrently filed this petition. Applicants further argued the rejections and objections made by the examiner. This amendment has not been acted on, but will be acted on subsequent to the mailing of this petition decision.

## DISCUSSION

It is noted first that although applicants made an election with traverse in response to the initial Office action setting forth a Lack of Unity requirement, no arguments for traverse were presented thus compromising applicants' rights to later traverse the requirement or file this petition. However the petition will be treated on the merits

A thorough review of the claims, as filed, and the prosecution has been made. It is clear that this application is subject to Unity of Invention review at each stage of prosecution. Initially the examiner divided the claimed Markush group of compounds/compositions contained in claims 1-85 into four groups, but did not identify any special technical feature for any of the groups; they were defined only by the values of certain substituents. It is not clear that these values serve to define a special technical feature. The examiner also invited applicants to identify a species if none of the groups included the species desired by applicants. In effect this was a request for an election of species from which examination could begin.

A review of the claims shows that independent Claim 1 is directed to a large number of compounds defined by a Markush group. Independent Claim 2 claims two individual species,

salts and solvates thereof. Claim 3, dependent from claims 1 and 2, adds a pharmaceutical carrier. Claim 4 claims a use of the compounds of claims 1 and 2. Claims 5-7 claim compounds of claims 1-3 (and are improperly multiply dependent) used for arrhythmia and ion channel modulation. Even numbered claims 8-84 depend on claims 1 and 2 and claim pharmaceutical compositions of claims 1 and 2 for treating various conditions and odd numbered claims 9-85 depend from their immediately preceding claim and are to a method of treating the condition identified.

Applicants' petition cites M.P.E.P. 1850, part D, which relates to Unity of Invention in Markush groups. The requirements are that (a) all alternatives have a common property or activity; and (b) that there be a common structure present shared by all alternatives or that they belong to a recognized class of chemical compounds.

Applicants' argument that all compounds possess a common utility or activity is severely questioned. Applicants suggest one common utility is treatment of arrhythmia. However applicants also claim more than 35 other conditions for which the compounds/compositions may be used. It is unlikely (and unsupported in the specification) that the same common structural feature provides activity or utility for all conditions claimed. It appears more likely that the values for variable A and other variables provide different utilities for different conditions.

Applicants suggest that the common structural element is an unsaturated carbocyclic ring structure of 5, 7 or 8 carbons having on adjacent carbons an amino group and an ether or ester group. Applicants are essentially correct that the 2-amino cycloalkyl esters or ethers form the only common structure present. In the absence of any prior art cited by the examiner it is not known whether this structure is known or not, although its simplicity suggests that it is known. If known, the structure cannot be a special technical feature which defines over the art and would thus establish that Unity is lacking. However, the examiner has failed to provide any prior art to substantiate such a holding.

Further, the examiner in the first Office action appears to have merely picked and chosen some variables in order to set forth a non-exhaustive restriction requirement, rather than a Lack of Unity requirement, under 35 U.S.C. 121. Such was improper. The examiner's statement of not setting forth all possible combinations of the variables and inviting applicants to, in essence, create their own group by electing a species from which to start examination and on which the examiner would build a subgenus was not proper. The examiner should have determined what the basic common structure is and then determined whether it defines over the art or not. If it does define over the art then all compounds/compositions having this structure would be patentable. If it does not define over the art then the differing values of one or more variables should have been used to establish one or more structures which do define over the art and thus establish a Lack of Unity between the different structures, but Unity within the structures.

The examiner, however, in effect, set forth an election of species requirement inviting applicants to identify a species from which examination should begin. However, election of species is not specifically provided for under Lack of Unity guidelines. This does not prevent an examiner from inviting applicants to assist by identifying a starting point for examination as has herein been done. However, having made such invitation and accepted such identification of a single

species to then limit applicants to an examiner created subgroup or subgenus of compounds/compositions is improper. Based on the identified species the examiner should have determined the differences between it and the structure common to all compounds and proceeded to determine patentability based on the minimum number of differences therebetween. In other words the examiner should have determined patentability of the species initially and then expanded patentability considerations by eliminating one or more structural differences until a compound is found which is not patentable over the prior art and based Lack of Unity thereon. If no prior art is found for the structure common to all, then all compounds should be deemed patentable.

#### DECISION

The petition is **GRANTED**.

**The application will be forwarded to the examiner for consideration of the amendment filed August 6, 2004, and further action not inconsistent with this decision.**

**No fee is required for this petition and the petition fee paid of \$130.00 will be credited to applicants' Deposit Account No. 03-1952, as directed.**

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 703-308-3824 or by facsimile sent to the general Office facsimile number, 703-872-9306.



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